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<i>.</i>			U.S. Pa	tent and Trad	PTO/SB/21 (0 ed for use through 07/31/2006. OMB 0651-0031 lemark Office; U.S. DEPARTMENT OF COMME
Under the Paperwork Reduction	on Act of 1995, no pe	ersons are required	to respond to a co		ormation unless it displays a valid OMB control nu
			Filing Date		10/801,623
TRANS	ATTIME	L			March 15, 2004
·FC	DRM		First Named	Inventor	Chong-Sheng YUAN
(to be used for all corre	spondence after ini	tial filing)	Art Unit		1651
		· ·	Examiner Na	me	S. Fernandez
Total Number of Pages in	This Submission	n 13	Attorney Doc	ket Number	466992001400
	ENC	LOSURES	(Check all t	hat apply	/)
X Fee Transmittal Form (duplicate)	1 page plus	Drawing(s)			After Allowance Communication to TC
Fee Attached	[Licensing-rel	ated Papers		Appeal Communication to Board of Appeals and Interferences
Amendment/Reply] [Petition			Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
After Final		Petition to Co			Proprietary Information
Affidavits/declara	ition(s)	Power of Attorney, Revocation Change of Correspondence Address		n Address	Status Letter
Extension of Time Req	uest	Terminal Disclaimer			X Other Enclosure(s) (please Identify below):
Express Abandonment	Request	Request for Refund			PTO/SB/08a/b Form (2 pages plus duplicate)
X Information Disclosure Statement (6 pages)		CD, Number of CD(s)			References (34) Return Receipt Postcard
Certified Copy of Priori Document(s)	ty	Landso	ape Table on (CD	
Reply to Missing Parts Incomplete Application		Remarks			
Reply to Missing Parts under 37 CFR 1.52 or 1.53 CUSTOMER NO. 25225				25225	
	SIGNATUR	E OF APPLICA	NT. ATTOR	NEY. OR	AGENT
im Name MORRIS	ON & FOERS		,	,,	
Signature Michael MICHAEL G SMITH, Roy NO. 44,422					
Printed name Peng Ch	en				, ,
Date Y January	17, 2006			Reg. No.	43,543
I hereby certify that this corre in an envelope addressed to shown below.	espondence is beir MS Amendment,	ng deposited with the commissioner for	he U.S. Postal S Patents, P.O. E	Service as Ex Box 1450, Ale	xpress Mail, Airbill No. EV 761643878 US, exandria, VA 22313-1450, on the date

PTO/SB/17 (12-04v2)

Approved for use through 7/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Effective on 12/08/2004.	Со	mplete if Know	/n
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).	Application Number	10/801,623	
FEE TRANSMITTAL	Filing Date	March 15, 200)4
For FY 2005	First Named Inventor Chong-Sheng YUAN		YUAN
F01 F1 2005	Examiner Name	S. Fernandez	
Applicant claims small entity status. See 37 CFR 1.27	Art Unit	1651	
TOTAL AMOUNT OF PAYMENT (\$) 180.00	Attorney Docket No.	46699200140	0
METHOD OF PAYMENT (check all that apply)	· ·		
Check Credit Card Money Order No	ne Other (please ide	ntify):	
x Deposit Account Deposit Account Number: 03-1952 Deposit Ac	count Name: M	orrison & Foers	ter LLP
For the above-identified deposit account, the Director i	s hereby authorized to: (ch	eck all that apply))
x Charge fee(s) indicated below	Charge fee(s) i	ndicated below, e	xcept for the filing fee
Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17	x Credit any over	payments	
FEE CALCULATION			
1. BASIC FILING, SEARCH, AND EXAMINATION FEES		•	
FILING FEES SE Small Entity Application Type Fee (\$) Fee (\$)	Small Entity	INATION FEES <u>Small Entity</u>) Fee (\$)	Fees Paid (\$)
Utility 300 150 500		100	<u> </u>
Design 200 100 100		65	
Plant 200 100 300	150 160	80	
Reissue 300 150 500	250 600	300	
Provisional 200 100 0	0 0	0	
2. EXCESS CLAIM FEES			Small Entity
Fee Description Each claim over 20 (including Reissues)			Fee (\$) Fee (\$) 50 25
Each independent claim over 3 (including Reissues)			200 100
Multiple dependent claims			360 180
	Paid (\$)	Multiple Depend	
21 -21 = x =			Fee Paid (\$)
Indep. Claims Extra Claims Fee (\$) Fee	Paid (\$)		
3. APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper listings under 37 CFR 1.52(e)), the application size fee d sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and	ue is \$250 (\$125 for small 137 CFR 1.16(s).	entity) for each a	additional 50
<u>Total Sheets</u> <u>Extra Sheets</u> <u>Number of each</u>	additional 50 or fraction ther (round up to a whole numbe		Fee Paid (\$)
4. OTHER FEE(S) Non-English Specification, \$130 fee (no small entity dis	count)		Fees Paid (\$)
Other (e.g., late filing surcharge): 1806 Submission of	•	e Statement	180.00
SUBMITTED BY			
Signature Michael Smith Ro, No 44,422 MICHAEL G. SMI	Registration No. 43,54	3 Telephone	(858) 720-5117
Name (Print/Type) Peng Chen		Date	January 17, 2006

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. 761643878 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: January 17, 2006 Signature:

Patent Docket No. 466992001400

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Chong-Sheng YUAN et al.

Serial No.: 10/801,623

Filing Date: March 15, 2004

For: METHODS AND COMPOSITIONS FOR

ASSAYING HOMOCYSTEINE

Examiner: S. Fernandez

Group Art Unit: 1651

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

Document No. 2 is a Chinese Patent Application, CN 1560610 A, entitled "Method for L-homocysteine assay and reagents thereof," published on January 5, 2005. Document No. 3 is a certified English translation of Document No. 2.

01/20/2006 HDERESS1 00000056 031952 10801623

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Axis-Shield ASA commenced an unfair competition action and a patent infringement action against General Atomics on October 8, 2001, based on U.S. Patent Nos. 5,631,127 and 5,958,717. This action was later dismissed without prejudice on March 22, 2002. Document Nos. 4-8 are from *Axis-Shield ASA vs. General Atomics*, dismissed without prejudice on March 22, 2002, in the United States District Court for the Southern District of California, Case No. 01 CV 1836 J (RBB).

General Atomics and Diazyme Laboratories Division commenced a declaratory relief action against Axis-Shield ASA on U.S. Patent Nos. 5,631,127, 5,958,717, 5,827,645 and 6,063,581. The action is currently pending. Document Nos. 9-13 are from *General Atomics*, Diazyme Laboratories Division vs. Axis-Shield ASA, currently pending in the United States District Court for the Northern District of California, San Francisco Division, Case No. C 05 4074 EDL.

Diazyme Laboratories is opposing Axis-Shield's patent in Europe, EP Patent No. 0 726 322. Document Nos. 14-16 are from an Opposition proceeding against EP Patent No. 0 726 322. The Opposition is currently pending.

- Diazyme Laboratories' Opposition Notice (Document No. 14) is based on the following prior art references:
 - o Tanaka et al., Analytical Letters (1981) 14:111-118 (Document No. 17 of the present Supplemental IDS)
 - o Selim and Greenberg, JBC (1958) 234:1474-1480 (Document No. 18 of the present Supplemental IDS)
 - o Kashiwamata et al., Biochim. Biophys. Acta (1970) 212:488-500 (Document No. 19 of the present Supplemental IDS)
 - o Binkley, JBC (1951) 101:531-534 (Document No. 20 of the present Supplemental IDS)

- Shimizu et al., Biotechnol. Appl. Biochem. (1986) 8:153-159 (Document
 No. 21 of the present Supplemental IDS)
- o Porter et al., JBC (1991) 32:21616-21625 (Document No. 22 of the present Supplemental IDS)
- o Trewyn and Kerr, Journal of Biochemical and Biophysical Methods (1981) 4:299-307 (Document No. 23 of the present Supplemental IDS)
- Loughlin et al., JBC (1964) 239:2888-2895 (Document No. 24 of the present Supplemental IDS)
- Graham, Trends Cardiovasc. Med. (1991) 1:244-249 (Document No. 25 of the present Supplemental IDS)
- o Garras et al., Analytical Biochem. (1991) 199:112-118 (Document No. 26 of the present Supplemental IDS)
- o Frisell et al., JBC (1953) 207:709-716 (Document No. 27 of the present Supplemental IDS)
- Sullivan and Hess, JBC (1936) 116:221-233 (Document No. 28 of the present Supplemental IDS)
- o EC4.2.1.22, www.chem.qmul.ac.uk/iubmb/enzyme/EC4/2/1/22.html (Document No. 29 of the present Supplemental IDS)
- Axis-Shield filed a Response to Diazyme Laboratories' Opposition Notice (Document No. 15)

- Diazyme Laboratories filed a Response to Axis-Shield's Response (Document No. 16). Diazyme Laboratories' Response is based on the following additional documents:
 - Yamaguchi and Hosokawa, Methods in Enzymology (1987) 143:395-403
 (Document No. 30 of the present Supplemental IDS)
 - Kotb and Kredich, J. Biol. Chem. (1985) 260(7):3923-30 (Document No.
 31 of the present Supplemental IDS)
 - o Tanaka et al., J. Applied Biochem. (1980) 2:439-444 (Document No. 32 of the present Supplemental IDS)
 - O US Patent No. 5,985,540 (Document No. 1 of the present Supplemental IDS)
 - o Bruton and Cox, Eur. J. Biochem. (1979) 100:301-308 (Document No. 33 of the present Supplemental IDS)
 - Homogeneous Enzymic Homocysteine Reagent package insert from Carolina Liquid Chemistries (Document No. 34 of the present Supplemental IDS)

This Information Disclosure Statement is submitted:

With the application; accordingly, no fee or separate requirements are required.
Before the mailing of a first Office Action after the filing of a Request for Continued
Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97
(e)(1) has been provided.

	Within	n three months of the application filing date or before mailing of a first Office Action
	on the	merits; accordingly, no fee or separate requirements are required. However, if
	applic	able, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
\boxtimes	After	receipt of a first Office Action on the merits but before mailing of a final Office Action
	or Not	tice of Allowance.
		A fee is required. A check in the amount of is enclosed.
	\boxtimes	A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to
		this submission in duplicate.
		A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is
		believed to be due.
	After	mailing of a final Office Action or Notice of Allowance, but before payment of the
	issue f	Fee.
		A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the
		amount of is enclosed.
		A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal
		form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 466992001400.

Dated: January <u>17</u>, 2006

Respectfully submitted,

Michael Smith Roy No. 44,422 MICHAEL G. SMITH

Peng Chen

Registration No.: 43,543 MORRISON & FOERSTER LLP 12531 High Bluff Drive Suite 100 San Diego, California 92130-2040

(858) 720-5117

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known		
Application Number	10/801,623	
Filing Date	March 15, 2004	
First Named Inventor	Chong-Sheng YUAN	
Art Unit	1651	
Examiner Name	S. Fernandez	
Attorney Docket Number	466992001400	

	U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-5,985,540	11-16-1999	Tan et al.	

		FOREI	GN PATENT	DOCUMENTS		
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	
Initials*	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)		Applicant of Cited Document	or Relevant Figures Appear	T ⁸
	2.	CN-1560610	01-05-2005	Wang Xuezhong		X
	3.	English Translation of CN 1560610	01-05-2005	Wang Xuezhong		

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	4.	Complaint For Patent Infringement And Unfair Competition And Demand For Jury Trial, filed October 9, 2001	
	5.	First Amended Complaint For Patent Infringement And Demand For Jury Trial, filed December 19, 2001	
	6.	Answer To Amended Complaint And Counterclaim; Jury Demand, filed January 8, 2002	
	7.	Plaintiff Axis-Shield ASA's Early Neutral Evaluation Conference Settlement Brief, filed March 11, 2002	
	8.	Stipulation For Joint Dismissal Without Prejudice Of Complaint And Counter-Claim; [Proposed] Order, filed March 22, 2002	
	9.	Complaint For Declaratory Relief, filed October 11, 2005	
	10.	Answer And Counterclaim And Of Axis-Shield ASA, filed October 27, 2005	
	11.	General Atomics' Reply To Counterclaim, filed November 16, 2005	
	12.	Reply And Counterclaim Of Carolina Liquid Chemistries Corporation, filed November 16, 2005	
	13.	Answer To Counterclaim Of Carolina Liquid Chemistries Corporation, filed November 17, 2005	
	14.	Notice of Opposition to EP Patent 0 726 322, filed January 16, 2004	
	15.	Patentee's Response to the Notices of Opposition, filed October 1, 2004	
	16.	Response to Patentee's letter dated October 1, 2004, filed July 11, 2005	
	17.	TANAKA et al., Analytical Letters (1981) 14:111-118	
	18.	SELIM and GREENBERG, JBC (1958) 234:1474-1480	
	19.	KASHIWAMATA et al., Biochim. Biophys. Acta (1970) 212:488-500	
	20.	BINKLEY, JBC (1951) 101:531-534	
	21.	SHIMIZU et al., Biotechnol. Appl. Biochem. (1986) 8:153-159	
	22.	PORTER et al., JBC (1991) 32:21616-21625	

Examiner	Date
Signature	Considered
1.00.1000	

Complete if Known Substitute for form 1449/PTO Application Number 10/801,623 March 15, 2004 **INFORMATION DISCLOSURE** Filing Date Chong-Sheng YUAN First Named Inventor STATEMENT BY APPLICANT Art Unit 1651 (Use as many sheets as necessary) Examiner Name S. Fernandez 2 2 Sheet of Attorney Docket Number 466992001400

23.	TREWYN and KERR, Journal of Biochemical and Biophysical Methods (1981) 4:299-307
24.	LOUGHLIN et al., JBC (1964) 239:2888-2895
25.	GRAHAM, Trends Cardiovasc. Med. (1991) 1:244-249
26.	GARRAS et al., Analytical Biochem. (1991) 199:112-118
27.	FRISELL et al., JBC (1953) 207:709-716
28.	SULLIVAN and HESS, JBC (1936) 116:221-233
29.	EC4.2.1.22, www.chem.qmul.ac.uk/iubmb/enzyme/EC4/2/1/22.html
30.	YAMAGUCHI and HOSOKAWA, Methods in Enzymology (1987) 143:395-403
31.	KOTB and KREDICH, J. Biol. Chem. (1985) 260(7):3923-30
32.	TANAKA et al., J. Applied Biochem. (1980) 2:439-444
33.	BRUTON and COX, Eur. J. Biochem. (1979) 100:301-308
34.	Homogeneous Enzymic Homocysteine Reagent package insert from Carolina Liquid Chemistries

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.